

Notice of Allowability

Application No.

10/084,639

Examiner

David A. Saunders, PhD

Applicant(s)

HAGEMAN ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 1/12/05.
2. ☒ The allowed claim(s) is/are 1-7,15,21,22,33 and 34.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with R.T. Apple on 4/18/05.

The application has been amended as follows:

At specification page 1, in the paragraph under "CROSS-REFERENCE TO RELATED APPLICATIONS", at line 2 thereof, after "2001", inserted --and now abandoned--. At line 3 thereof, after "2000", inserted -- and now abandoned--.

In claim 1, lines 5-6 deleted "*fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,*", and inserted therefor --fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,--. At line 6, deleted "*serotransferrin*", and inserted therefor --serotransferrin--.

In claim 7, lines 3-4 deleted "*fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,*", and inserted therefor --fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,--. At line 4, deleted "*serotransferrin*", and inserted therefor --serotransferrin--.

In claim 15, lines 3-4 deleted "*fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,*", and inserted therefor

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--fibulin-3, beta-crystallin A2, beta-crystallin A3, beta-crystallin A4, beta-crystallin S, calreticulin, 14-3-3 protein epsilon,--. At line 4, deleted "*serotransferrin*", and inserted therefor --serotransferrin--.

In claim 21, line 2 deleted "urine, eye fluid," and "lymph fluid,".

In claim 22, line 2 deleted "*serotransferrin*" and inserted therefor --serotransferrin--. At line 2 deleted "or an antigenic". At line 3 deleted "fragment of *serotransferrin*". At line 4, deleted "*serotransferrin*" and inserted therefor --serotransferrin--. At line 4, deleted "or a" and all words thereafter. Deleted all of line 5, but for the period.

The above changes to claims 1, 7 and 15 have been made because the recited Markush group members are proteins, not names of microorganisms.

The above changes to claim 21 have been made to avoid claim duplication.

The above change to claim 22 has been made to render its scope narrower than that of claim 4.

The following is an examiner's statement of reasons for allowance:

The amendment has overcome all 112 issues of record. The amendment of claim 1 has clearly overcome prior art rejections stated over Hageman and over Hageman in view of Schuurs et al. With respect to the rejections over Chen et al and Gurne et al, these references each identify autoantibodies reacting with antigens identified by m.w. on western immunoblots. None of these antigens can be identified as corresponding to those recited in instant claim 1. Regarding Penfold et al, this reference shows immunohistochemical staining by autoantibodies; the major staining appears to be against the protein GFAP. It is not clear what other antigens may have been stained, and there can be a difference in staining patterns depending upon what autoimmune

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serum sample is studied. Gurne et al also shows immunohistochemical staining with autoimmune sera; this reference notes that the predominant pattern observed differed from that of Penfold et al (page 606, col. 2). Immunohistochemical staining patterns are thus inconsistent, and it is not clear what antigens are being stained in the tissue sections. It is further to be noted that, in the preparation of any tissue section, even an unfixed cryostat section, there can be denaturation of one or more antigens; thus there is no evidence that any of the tissue sections of Penfold et al or Gurne et al showed reactivity with autoantibodies against any of the antigens recited in claim 1.

As the claims are renumbered at allowance, claims 33-24 will immediately follow 2, and claim 22 will immediately follow 4.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAS 4/18/05.

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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